Federal Wide Assurances

- What is an FWA?
- Who needs an FWA?
- What does an FWA say?
- Application Procedure

What is an FWA?

- Signed document

- Assures Institution will comply with U.S. federal regulations for protection of human subjects in research.
  - Common Rule (for NIH, 45 CFR 46)
  - FDA, 21 CFR subpart 50
  - Others as applicable

Who Needs an FWA?

Institutions **engaged** in NIH-conducted or supported human subjects research:

(a) employees or agents interact with human subjects for research purposes

(b) employees or agents obtain individually identifiable private information about human subjects for research purposes

(c) receives an award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

Both U.S. and Foreign!

Steps for Completing an FWA

1. Read the Instructions and the Terms of Assurance.

2. Identify registered IRB/EC or Register Institution's IRB/EC

3. Complete FWA form. (Paper or Online)

4. FAX signed form to OHRP
   - (online form – print, sign and fax)
5. Track approval process online

What Does an FWA Say?

FWA terms for non-U.S. Institutions

1. Human Subjects Research Must Be Guided by Ethical Principles
   e.g. Declaration of Helsinki, Belmont Report

2. Applicability
   Federally-supported defined as U.S. Government providing any funding or other support

3. Compliance with Laws, Regulations, Policies, and Guidelines
   U.S and local

FWA terms for non-U.S. Institutions

4. IRB/IEC Written Procedures

For reporting unanticipated problems, serious or continued non-compliance, suspensions, etc to IRB, OHRP, federal agency

5. Scope

Research reviewed, prospectively approved, and subject to continuing review at least annually

6. Informed Consent Requirements

Sought from all potential participants + documented

FWA terms for non-U.S. Institutions

7. Considerations for special class of subjects (45 CFR 46 parts B, C, D)

8. Requirement for assurances for collaborating institutions

9. Written agreements with independent investigators not affiliated with institution

FWA terms for non-U.S. Institutions

10. Institutional Support for the IRB(s)

11. Compliance with Assurance Terms

12. Assurance Training

IRB Chair, Institutional official, Human Subject Protection Officer

FWA terms for non-U.S. Institutions

13. Educational Training
    Investigators, IRB members, and others

14. Renewal of Assurance
    Every three years

Steps for Completing an FWA

1. Read the Instructions and the Terms of Assurance.

2. Identify registered IRB/EC or Register Institution's IRB/EC

3. Complete FWA form. (Paper or Online)
   - Legal name of Institution (just one!)
   - Designate ethical principals institution will follow
   - Indicate procedural standards (45 CFR 46, ICH GCP)
   - All parts covered (e.g. schools, hospital, etc)
   - Designate IRB(s)
   - Identify Human Protections Administrator
   - Identify Signatory Official (high level)
   - Indicate training

4. FAX signed form to OHRP
   - (online form – print, sign and fax)
5. Track approval process online

OHRP Website

http://www.hhs.gov/ohrp/